INTERNATIONAL BOTTLED WATER ASSOCIATION

Written Testimony of
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Chairman Stupak, Ranking Member Walden, and Members of the Subcommittee, my name is Joseph K. Doss. I am President and CEO of the International Bottled Water Association (IBWA)[1] in Alexandria, Virginia. Thank you for the opportunity to provide the bottled water industry's perspective on the regulation of bottled water, particularly as compared with public drinking water regulation.

I. Overview of the Bottled Water Industry

Background

IBWA appreciates the opportunity to provide the Subcommittee with our views on the very important issues being considered at this hearing. Bottled water is a safe, convenient, healthful, regulated food product that consumers find refreshing and use to stay hydrated. People choose bottled water for several reasons, including taste, quality, and convenience. Bottled water is also an alternative to other packaged beverages when consumers want to eliminate or moderate calories, caffeine, sugar, artificial flavors or colors, alcohol and other ingredients from their diets. The consumption of water, whether from the bottle or the tap, is a good thing, and any actions that discourage people from drinking bottled water are not in the public's interest.

The bottled water industry is the second largest commercial beverage category by volume in the United States. Nearly all bottled water sold in the United States is sourced domestically. Only approximately two percent of the total volume is comprised of imported bottled water.

[1] IBWA is the trade association representing all segments of the bottled water industry, including spring, artesian, mineral, sparkling, well, groundwater and purified bottled waters. Founded in 1958, IBWA member companies include United States and international bottlers, distributors and suppliers. Bottled water companies produce a packaged food product that is comprehensively and stringently regulated by the United States Food and Drug Administration (FDA). IBWA is committed to working with state and federal governments to establish and implement stringent standards for assuring the production and sale of safe, high-quality bottled water products. In furtherance of this objective, IBWA has developed and published a Code of Practice (available at IBWA's website: http://www.bottledwater.org/public/policies_main.html), which establishes standards of bottled water production, quality, and distribution that must be met by IBWA members. In some cases, the IBWA Code of Practice is even more stringent than state and federal regulations. As a condition of membership, IBWA bottlers must submit to an annual plant inspection by an independent third party to determine compliance with the Code of Practice and all applicable FDA regulations.

According to the Beverage Marketing Corporation, in 2008 the total volume of bottled water consumed in the United States was 8.7 billion gallons, a one percent decrease from 2007. That translates into an average of 28.5 gallons per person. Sales revenues for the United States bottled water market in 2008 were approximately $11.2 billion (in wholesale dollars), a 3.2% decrease over the previous year. Bottled water consumption is about half that of carbonated soft drinks (CSD's) and only slightly ahead of milk and beer.

The United States bottled water market is truly consumer driven. This is, in large part, because people are making healthier beverage choices. The strength of this consumer self-generated demand is illustrated by the relatively modest amount spent on bottled water advertising. The 2007 bottled water advertising expenses totaled only $54.5 million.[2] For comparison purposes, $803 million was spent on advertising carbonated soft drinks (nearly fifteen times that for bottled water), and advertising expenses for beer totaled $1.187 billion (approximately 20 times that for bottled water).

Bottled Water Industry Profile

The bottled water industry has two primary business models. The first model is home and office delivery (HOD) of the three and five gallon bottles used with water coolers, which accounts for about 20% of the bottled water market. This segment of the bottled water market has been providing consumers with safe, quality products for over one hundred years in the United States. The second model is retail sales of bottled water to consumers in 2 ½ gallon, 1 gallon, and smaller sized bottles (e.g., half liter and one liter), generally through retail, convenience, and grocery stores, as well as vending machines. Retail business accounts for about 80% of the bottled water market and is the largest and fastest growing segment of the United States bottled water industry.

The sources for bottled water products that comprise the United States market can be divided into two fundamental categories, which are aligned with the Food and Drug Administration's (FDA) standards of identity. The largest segment of the bottled water industry – the natural waters -- is sourced from groundwater. They are artesian, mineral, sparkling, spring and well water. The remainder of the market is processed water, such as purified, sterile or drinking water. Groundwater sources, which are used by an estimated two-thirds of bottled water companies, are exclusively from underground aquifers, while processed water sources can be from either groundwater or municipal water systems.

Bottlers of natural waters have made extensive investments in developing groundwater sources, and have been at the forefront of legislative and regulatory efforts to encourage states to enact groundwater management programs that help ensure the sustainability of this important resource. From the source, the water is moved to the bottling plant, whether by tanker truck or pipe, where, if needed for added safety, it is disinfected. The water is then placed in a sealed sanitary container in the filling room of the bottling plant. A similar process is followed if the source is a public water system, with the exception of the added processing steps mandated by the United

[2] Beverage Marketing Corp.

States Food and Drug Administration (FDA) that must be employed to meet the purified or sterile standard of the U.S. Pharmacopeia 23rd Revision, e.g., distillation, reverse osmosis, or de-ionization.

Bottled water companies in the United States are primarily family owned and operated small businesses. Over 60% of the IBWA bottler members have annual sales of less than $1 million and 90% have sales less than $10 million. Almost all bottled water brands are sold on a local or regional basis, with the exception of imports and purified waters.

II. Regulatory Framework

A. Bottled Water is a Regulated Food Product

Bottled water is comprehensively and stringently regulated in the United States at both the federal and state levels, which helps ensure its safety and quality. At the federal level, bottled water is regulated as a packaged food product under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301 *et seq*., and several parts of Title 21 of the Code of Federal Regulations (CFR). There are four pillars that support the federal bottled water regulatory framework: general food regulations, specific bottled water Good Manufacturing Practices, bottled water Standards of Identity, and bottled water Standards of Quality.

First, as a packaged food product, bottled water must comply with the general food provisions under FFDCA and accompanying regulations. The FFDCA defines "food" as "articles used for food ***or drink*** for man or other animals ...."[3] Thus, all food and beverage products are regulated under the same statutory regime, and bottled water is no different in this respect than juice, carbonated soda, or energy drinks. Bottled water is subject to the same general FFDCA prohibitions against adulteration and misbranding as other beverage products, and is subject to the same general requirements for ingredient labeling, nutrition labeling, and product claims as other beverage products, as well as good manufacturing practices. From a market and legal perspective, bottled water is regulated the same as other beverages such as soft drinks, teas, and juices, which have water as their primary ingredient.

Bottled water containers, as with all food packaging materials, must be made from FDA-approved food contact substances. Thus, the plastic and glass containers that are used for bottled water products have undergone FDA scrutiny prior to being available for use in the market place. FDA has determined that the containers used by the bottled water industry are safe for use with food and beverage products, including bottled water, and that they do not pose a health risk to consumers. FDA is continually reviewing published scientific studies on food contact substances and also working with other federal and international agencies in research on health impacts for a variety of subsets of the general population. FDA has rigorous standards for research and evaluation of risk for food contact substances. The bottled water industry and others in the food industry rely on FDA to evaluate and determine which substances are safe to be used in contact

[3] 21 U.S.C. § 321(f) (emphasis added).

with food. All of the bottled water industry's packaging containers have been determined to be safe by FDA.

B. Bottled Water Good Manufacturing Practices

The second pillar in the federal bottled water regulatory framework can be found in FDA's bottled water good manufacturing practices. FDA's testing frequency and other parameters are specified in 21 C.F.R. Part 129, as part of the Good Manufacturing Practices (GMP) for bottled water. Bottled water is one of only a few food products with its own specific GMP regulations. Indeed, 21 C.F.R. Part 129 contains GMP's specific to bottled water. This section entitled "Processing and Bottling of Bottled Drinking Water" sets guidelines for:

- Bottled Water Plant Construction and Design [including separation of the bottling room (a fill room), protection of processing operations, adequate ventilation and enclosure of washing and sanitizing operations]. These requirements are very specific in the construction of a bottled water facility and must be met by every producer of bottled water, regardless of size or volume.
- Sanitary Facilities.
    - Source water must be obtained from an approved source and conform to applicable state and local laws and regulations.
    - Operations water, if different from source water, must also be obtained from an approved source and conform to applicable state and local laws and regulations.
    - Required testing of source water and finished product includes testing for chemical parameters once a year, rather than over a number of years as with public water systems; radiological testing once every four years; and microbiological testing once a week.
    - Sampling and analytical methods used must be those recognized and approved by the government agency of jurisdiction.
- Sanitary Operations.
- Equipment Design and Construction.
- Production and Process Controls (including water analysis, sampling and analytical methods, sampling and inspection of containers and closures, and record keeping).

Disinfection and Treatment

FDA's bottled water regulations establish stringent standards of quality but do not mandate any particular type of treatment techniques to meet those standards. Bottled water products - whether from groundwater or public water sources - are produced utilizing a multi-barrier approach. From source to finished product, a multi-barrier approach helps prevent possible harmful contamination to the finished product as well as storage, production, and transportation equipment. Measures in a multi-barrier approach may include one or more of the following: source protection, source monitoring, reverse osmosis, distillation, micro-filtration, carbon filtration, ozonation, ultraviolet (UV) light or other safe and effective methods. Many of the steps in a multi-barrier system may be effective in safeguarding bottled water from microbiological

and other contamination. The piping in and out of plants, as well as storage silos and water tankers, are also maintained through regular sanitation procedures. In addition, bottled water products are bottled in a controlled, sanitary environment to prevent contamination during the filling operation.

In addition to a multi-barrier approach, members of IBWA are required to employ a Hazard Analysis Critical Control Point (HACCP) approach to quality assurance. (FDA does not currently require a HACCP program for most food products, including bottled water, but it is mandated by the IBWA Code of Practice). This practice scrutinizes the steps involved in the production process – from source to finished product – that are critically important to the safety of the product and puts in place systems to help ensure that those safety and quality control processes are functioning effectively. Identification of risk and severity of health effects and control measures for specific biological, chemical and physical agents are included. Widely used in the food and pharmaceutical industries, FDA considers HACCP a comprehensive method for assuring product safety. IBWA supports the provisions of HR 2749, the Food Safety Enhancement Act, which would require all food manufacturers to conduct a hazard analysis and establish and maintain preventive controls. Such pro-active procedures will assist producers in managing the risk of contamination and reduce the need to recall food products.

Differences Between Bottled Water and Public Drinking Water Monitoring

The FDA Standards of Quality for bottled water as contained in 21 C.F.R. § 165.110 (b) apply to all containers of bottled water sold in the United States. There are no waivers, or averaging of test results, or exemptions to the standards. Since the FDA bottled water standards of quality apply to each container of bottled water, anyone is able to have an analysis done on any specific bottle of water and determine if it meets those standards. This is very different from public water systems. You cannot take a sample from your faucet and have it analyzed to determine compliance with the public drinking water standards because most public water system testing standards apply to the point of distribution and not the point of consumption. In addition, public water systems are permitted to average test results for many contaminants over a 12 month period to determine compliance. They are often subject to reduced monitoring requirements, and are often granted testing waivers. Both bottled water and public drinking water regulatory requirements for testing and monitoring are required by law to be equally protective of public health. In addition, IBWA's Code of Practice is even more stringent than the FDA requirements for testing and monitoring.

Bottled water is frequently tested throughout its production. To get an accurate picture and comparison of the frequency of testing between bottled water and public water systems, one should examine volume produced, or better yet, consumed. The entire bottled water industry in the United States annually produces approximately the same volume of water as a city of 150,000 people uses in the same time period. In addition, bottled water companies do not have waivers or exceptions available to them, as public water systems do.

For coliform testing, for example, the City of New York produces 1.086 billion gallons of tap water per day and is required to perform a minimum of 480 microbiologic tests, which represents

one test per 67.875 million gallons produced. If coliform testing for bottled water was done on a volume basis, a large bottler producing 250,000 gallons per day would be required to perform at least one microbiological test per 1.875 million gallons or over 30 times as many tests per gallon of water than a public water system.

A comparison of chemical testing yields similar conclusions when frequency in terms of volume of water is considered. The National Primary Drinking Water Regulations (NPDWRs) provide a public water system that uses groundwater with opportunities for monitoring waivers and reductions in testing frequency. FDA does not permit reduction of testing frequency to less than once per year, unless a state having jurisdiction over bottled water specifically issues such a waiver or reduction in monitoring. For example, for inorganic chemicals such as arsenic, cadmium, chromium, and mercury, a municipal water system with a groundwater source may receive permission from a state for a reduction in monitoring from every year to once every three or even nine years. Ironically, the only time that the same public water system source monitors for these chemicals more frequently than a bottled water source is when the municipal water system exceeds the MCL for any of the chemicals, at which time the NPDWRs require four consecutive quarters of testing for the chemical to demonstrate compliance with the MCL before a reduction can be considered again. Bottled water must be tested for these same chemicals annually, without any opportunity to request a reduction in testing frequency from FDA. In terms of comparing volumes, a municipal water system that distributes 5 million gallons of water per day and tests for inorganic chemicals every three years would test one sample for every 5.475 billion gallons of water. If the frequency is reduced to every nine years, the municipal water system would test one sample for every 16.425 billion gallons of water. The bottled water facility described above would test for the same inorganic chemicals every 91.25 million gallons, or over 50 times as many test per gallon of water, with no reduction in monitoring frequency under FDA's regulations.

Most states have issued statewide or use waivers for certain synthetic organic chemicals (SOCs) for municipal water system source waters. Therefore, they do not test source water for chemicals such as glyphosate, endothall, or 2,3,7,8-tetrachlorodibenzo-p-dioxin ("Dioxin"). Bottled water sources must be tested for these chemicals annually, unless a state drinking water agency has specifically issued a waiver for the bottled water company's ground water source. However, this does not occur frequently, as most bottled water sources are regulated by state agencies that regulate food products, not public water systems, and these agencies have no authority to issue those exemptions or waivers under FDA's regulations. Bottled water finished products are not eligible for waivers, and must be tested annually. In contrast, a public water system groundwater system must collect only one or two post-treatment samples (depending on populations served) at the entry point into the distribution system for SOC analysis during each three-year monitoring period.

Radiological testing is required for both public water system and bottled water ground water sources. But, once again, there is a difference in testing frequency. Municipal water systems must test most radiological parameters once every four years. FDA, on the other hand, requires source water testing every four years, but finished product water must be tested annually.

C. Standards of Identity

The third pillar in the federal bottled water regulatory framework is the Standards of Identity. FDA has promulgated Standards of Identity regulations that define what a given food product is, its name, and ingredients that must be used, or may be used in the manufacture of the food. In 1995, FDA established standard of identity regulations for bottled water. The Standard of Identity encompasses (1) a general description of bottled water; (2) names that may be used to identify bottled water products and what the terms mean (e.g., "bottled water," "drinking water," or alternative terms such as "purified water" or "spring water"); and (3) FDA requirements for "other label statements" specific to bottled water products. 21 C.F.R. § 165.110 (a) contains the standard of identity for bottled water. It provides uniform definitions for the following bottled water classifications: bottled, drinking, artesian, groundwater, distilled, deionized, reverse osmosis, mineral, purified, sparkling, spring, sterile and well water.

The FDA definition of bottled water is "water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents." Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii).[4]

Labeling

The current system of federal labeling laws and regulations protects the public health (including providing consumers with useful product information) and permits bottled water companies to sell their products in an efficient and cost effective manner in interstate commerce. All packaged foods and beverage products, including bottled water, have extensive labeling requirements, including a statement of identity, compliance with the applicable definitions in the Standards of Identity, ingredient labeling, name and place of business of the manufacturer, packer or distributor, the product's net weight, and if required, nutrition labeling. Any other information FDA may wish to require by regulation must be considered a material fact, the absence of which will result in misleading labeling for failure to reveal a material fact. Thus, if consumers are interested in more information about their choice of bottled water, they have the means to contact the manufacturer or distributor and request it.

FDA **does** require that the source be included on bottled water labels in a very specific instance. If a bottled water product's source is a municipal water system and the finished bottled water product does not meet the FDA Standard of Identity for purified or sterile water, it must indicate on the label that it comes from a public water system source.[5] Bottled water from a public water system source that is minimally treated to meet the bottled water quality standards would likely be labeled "drinking water." Since public water systems are not likely to meet the bottled water standards for purified water (United States Pharmacopeia 23rd Revision) or any other standard of identity, the source becomes a material fact, the absence of which would make the product misbranded. The FDA Standards of Identity provide consumers with a clear and concise

[4] 21 C.F.R. § 165.110 (a)
[5] 21 C.F.R. § 165.110 (b)(3)

description of what type of bottled water they are purchasing. All spring water, purified water, mineral water, and other types of bottled water must all meet the same standards in order to claim a specific type of bottled water. Thus, consumers can have confidence that all products labeled "purified water" must meet the same FDA Standard of Identity and all products labeled "spring water" must be able to document a hydrological connection of the bottled water's source with a spring that must continue to flow to the surface from an underground aquifer.

A bottled water product must meet the appropriate Standard of Identity and bear the required name on its label or it may be deemed misbranded under the FFDCA.[6] By law, FDA's standards of identity regulations pre-empt state laws that are different from the FDA regulations.[7] In promulgating the standards of identity and the labeling requirements for bottled water, FDA solicited, received and responded to numerous recommendations and suggestions on bottled water nomenclature and regulatory requirements. In fact much of the pre-amble to the final rule discusses the standards of identity and labeling issues.[8] The issue of whether or not to require the source of the main ingredient (water) to be listed on the label was considered and rejected specifically by FDA. IBWA concurs with the FDA conclusion, as follows:

> "Therefore, the agency concludes that the absence of information concerning the exact water source (e.g., specific municipal source, the well number, spring's legal name, address of the source) is not a material omission that would render the labeling misleading because bottled water must meet FDA's requirements which provide the consumer with assurances as to the safety, quality, and type of source. While the agency recognizes that some States require the geographic source identity, FDA simply is not persuaded that the additional information is a material fact that must be disclosed.
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> The brand name and the name of the manufacturer distinguish bottled waters as much as specific source labeling would. According to § 101.5(a), the label of a food in packaged form must specify conspicuously the name and place of business of the manufacturer, packer, or distributor. This labeling requirement provides consumers with the necessary information to contact the firm and obtain information (e.g., the name and location of the source, the well number, or the spring's legal name) that is not provided on the label if they are interested. Therefore, FDA concludes that there is no basis on which to require that information concerning the specific source of bottled water appear on the label."[9]

D. Bottled Water Quality

The fourth pillar of the federal regulatory framework for bottled water is the standards of quality. FDA establishes standards of quality regulations that set the allowable levels of substances that may be in a given food product. 21 C.F.R. § 165.110(b) contains the FDA Standards of Quality for bottled water. This regulation goes on for many pages and establishes quantifiable limits for microbiological, physical, chemical, and radiological substances for both source water and

[6] 21 U.S.C. § 343 (g)(1).
[7] 21 U.S.C. § 343-1 (a)(1)
[8] Beverages: Bottled Water: Final Rule, 60 Fed. Reg. § 57076 (November 13, 1995)
[9] 60 Fed. Reg. § 57104 – 57105 (November 13, 1995)

finished bottled water products. FDA has established standards for more than 90 substances pursuant to the Standards of Quality for bottled water. As FDA explained in its final rule amending the Standard of Quality for arsenic, the Standards of Quality regulations for bottled water are issued under the authority of the Standards of Identity and, therefore, pre-empt state laws that conflict with the FDA Standards of Quality.[10]

Most FDA bottled water quality standards are the same as EPA's maximum contaminant levels (MCL) for public water systems. The few differences are usually the result of the substance not being found in bottled water or the substance is regulated under another provision of law such as FDA's food additives program. [11] And, in some instances, FDA bottled water Standards of Quality are more stringent than EPA's public drinking water standards (e.g., copper, fluoride, lead, nickel and phenols).

DEHP (Di(2-ethylhexyl) phthalate, or Bis 2-ethylhexyl phthalate) is an example of a substance for which EPA has issued a regulation for tap water but FDA has not promulgated a similar standard of quality for bottled water. The three principal materials used in plastic containers in the bottled water industry -- polyethylene terephthalate (PET), polycarbonate, and high density polyethylene (HDPE) – do not contain DEHP or any other phthalate chemical. Therefore, DEHP is not likely to be found in bottled water products. The EPA MCL for DEHP in tap water is 6 parts per billion (ppb). In an effort to maintain parity with the EPA tap water standards, IBWA adopted an identical standard in our Code of Practice prior to 1998, which all members must meet as a condition of membership.

(Note: A complete list and a comparison of the FDA standards of quality for bottled water, the EPA maximum contaminant levels (MCL), and the IBWA standards of quality can be found in the attached Appendix A of the IBWA Code of Practice. In addition, attached is a Comparison of US FDA SOQs and US EPA MCLs with IBWA Code of Practice SOQs - revised 7/2007)

Equivalency with Public Drinking Water Standards

Section 410 of FFDCA requires FDA to review all U.S. Environmental Protection Agency (EPA) National Primary Drinking Water Standards (NPDWS) for public water systems to determine their applicability to bottled water. If FDA determines that the NPDWS is applicable to bottled water, it must establish standards of quality for bottled water that are as stringent and protective of public health as the EPA's standards for public drinking water. If FDA fails to act within 180 days of the effective date of any new EPA NPDWS for public water systems, FDA must then apply the new NPDWS to bottled water.

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[10] Beverages: Bottled Water, 70 Fed. Reg. § 33694, 33699- 33700 (2005).

[11] FDA did not establish an allowable level for acrylamide and epichlorohydrin because EPA determined that establishing MCLs for these chemicals (used as flocculents in public drinking water) was not feasible, and because FDA regulations issued under the Food Additives Amendment of 1958 (Pub. L. 85-929) prohibit unsafe use of acrylamide and epichlorohydrin (as flocculents) in the production of bottled water. Regulations governing food additives can be found in 21 C.F.R. §§170-180. See 21 U.S.C. §§ 348(c)(3)(A).

As noted, Section 410 of the FFDCA was enacted by Congress to ensure that FDA's regulation of bottled water is at least as protective of the public health as EPA's regulation of public water systems.[12] Key elements include:

1. Under Section 410, whenever EPA issues a primary drinking water regulation under section 1412 of the Safe Drinking Water Act that establishes a "maximum contaminant level" (MCL) or "treatment technique" for a contaminant, FDA is required to either: (a) publish a standard of quality for that contaminant for bottled water; or (b) make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled drinking water.

2. FDA is required to publish either the standard of quality or the finding that such regulation is not necessary not later than 180 days before the EPA regulation becomes effective. If FDA fails to act within that time, then the MCL's and/or treatment techniques established by the EPA become applicable to bottled water as a matter of law. If this happens, FDA – not EPA – would be responsible for enforcing the EPA standard or treatment technique made applicable to bottled water by operation of law.

3. As noted above, the purpose of Section 410 is to ensure that bottled water is regulated at least as stringently as public water systems. If EPA sets an MCL, and FDA determines that such MCL is applicable to bottled water, then FDA is required to set an allowable level that is "no less stringent" than the MCL set by EPA. Similarly, if EPA establishes a treatment technique, and FDA determines that such treatment technique is applicable to bottled water, then FDA is required to set requirements "no less protective of the public health" than the treatment technique established by EPA.

Examples of how Section 410 has operated are as follows:

1. <u>FDA establishes a standard of quality regulation.</u> FDA promulgated a regulation establishing a standard of quality for arsenic of 10 ppb on June 9, 2005,[13] which became effective on January 23, 2006. This was in response to EPA's issuance of a revised arsenic standard for public water systems – at the same level of 10 ppb - that also became effective on January 23, 2006.[14]

   On May 29, 2009, FDA promulgated a regulation establishing a zero tolerance for *E. coli* in the sources for bottled water, as well as in finished product. The rule becomes effective for bottled water on December 1, 2009.[15] The regulation provides a standard

[12] Federal Food, Drug, and Cosmetic Act § 410, 21 U.S.C. § 349 (2005).
[13] Beverages: Bottled Water, 70 Fed. Reg. § 33694 (2005)
[14] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. § 6976 (2001)
[15] 74 Fed. Reg. § 25651 (May 29, 2009)

of quality as protective of public health as the EPA's Ground Water Rule that also becomes effective on December 1, 2009.[16]

2. FDA determines EPA action not applicable to bottled water. After reviewing EPA's Interim Enhanced Surface Water Treatment Rule (IESWTR), FDA concluded in a *Federal Register* notice on July 5, 2001,[17] that it would not apply to bottled water, since bottled water is produced either from groundwater sources that are not under the influence of surface water or from municipal water systems that would have already complied with the IESWTR.

3. FDA takes no action. Following EPA's issuance of MCL's and monitoring requirements for nine contaminants, FDA did not amend its Standard of Quality regulations before the statutory deadline. In that case, Section 410 operated and the MCL's established by EPA, as well as, the monitoring requirements, became applicable to bottled water, as a matter of law.[18] This is the only occasion where FDA has not acted within the statutory timeframe.

Total Coliform and *E. Coli*

As mentioned above, FDA has just recently established a zero tolerance standard of quality for *E. Coli* in bottled water. However, since 1995, FDA has had a microbiological standard of quality for coliform in bottled water (21 C.F.R. § 165.110 (b)(2)) that requires bottled water to meet the following standards, depending on the type of analysis being done:

> "i) Multiple-tube fermentation method. Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or
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> (ii) Membrane filter method. Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters."

On May 29, 2009, FDA published additional microbiological requirements rule that require bottled water manufacturers to test both source and finished product for the presence of total coliform bacteria. This new rule is effective December 1, 2009.[19]

The new rule establishes a "zero tolerance" standard for *Escherichia coli (E. coli)* for source and finished product. It mandates that if a bottled water source tests positive for *total coliform*, every total coliform-positive sample must be confirmed for presence or absence of *E. coli*. The rule

[16] 71 Fed. Reg § 65574 (November 8, 2006)
[17] Beverages: Bottled Water, 66 Fed. Reg. § 35439 (2001).
[18] Bottled Water: Monitoring Requirements, 63 Fed. Reg. § 42199 (1998).
[19] 74 Fed. Reg. § 25651 (May 29, 2009)

also provides specific detail on what must be done to correct and return a source into service after a positive *E. coli* result.

Bottled water manufacturers that obtain their source water from a natural source (e.g., spring or artesian well) or any other source other than a public water system (PWS) must test their source water at least weekly for total coliform. If that source water is total coliform positive, the bottled water manufacturer must conduct follow-up testing to determine whether any of the coliform organisms are *E. coli*. Source water found to contain *E. coli* will not be considered water of a safe, sanitary quality as required by FDA for use in bottled water. FDA's decision to include this provision is based primarily upon the legislative and regulatory requirements under Section 410 of FFDCA to demonstrate that the rule provides at least equivalent protection of public health when compared to the USEPA Ground Water Rule, which also becomes effective on December 1, 2009.

In 2001, IBWA adopted a zero tolerance standard of quality for *E. coli* for its members and provided clear guidance in how to confirm the presence or absence of this more accurate indicator of fecal contamination. IBWA has urged FDA to establish a zero tolerance for *E. coli* for several years and fully supported the adoption of the new rule.

The EPA rule for public drinking water requires that a ground water-based PWS follow up *E. coli*-positive test results or possibly other fecal indicators with a series of actions, including additional testing and corrective action (such as an alternate source, remedying the deficiency or providing treatment to achieve 4-log virus inactivation). However, the EPA rule does not prohibit such a contaminated source from being used again in the future as long as corrective action has been implemented. To achieve at least an equal level of public health protection, while not having to rely on a "reactive" set of measures, FDA simply established an absolute standard of quality at both the source and for finished product. As a result of this strict approach, any non-PWS bottled water source shown to be positive for *E. coli* is considered unsuitable for use for bottled water production. In order to resume use of the same source for bottled water production, FDA mandates that appropriate corrective actions be implemented and followed by a defined testing regime showing the absence of *E. coli*.

Before a bottler can use water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its reoccurrence. This provision is intended to eliminate microbial risk to the product from a contaminated source that relies solely on the bottling process to eliminate the contaminant. While FDA permits bottlers to remove certain compounds ("undesirable elements") prior to bottling the product, this new rule does <u>NOT</u> permit treatment as an acceptable means to "rectify" the problem. A source previously found to contain *E. coli* can only be considered again for bottled water production when:

a. Corrective actions have been implemented
b. Five samples collected over a 24-hour period from the same sampling site are *E. coli* negative.

This new regulation is ***more protective*** of public health than the corresponding rule for public drinking water, because it does not permit the continued use of a contaminated source for bottling purposes.

Microorganisms

If pathogenic microorganisms are present in bottled water and potentially injurious to public health, FDA has authority to classify the product as adulterated[20] and subject it to enforcement action, such as seizure of the product.[21] This would apply to such microorganisms as *Cryptosporidium*, *Legionella, Giardia lamblia,* and other pathogens that are generally found in surface water. However, the Agency has not established standards of quality for these three microorganisms because bottled water is produced from either groundwater sources that, by definition, must not be under the influence of surface water,[22] or from municipal water systems that are already compliant with EPA's Surface Water Treatment Rule.[23]

III. Oversight and Inspections

Inspections

In recent years, FDA has increased the frequency of inspections of all food facilities and is working with state agencies with jurisdiction over food products through contracts to augment the FDA Office of Regulatory Affairs inspectors with state personnel. In addition, 24 states require out-of-state bottlers to be either licensed or permitted to do business in the state and as a condition of obtaining a permit, they require proof of inspection. The 26 states that do not require out-of-state bottlers to be permitted regulate the in-state bottlers and use either state or county inspectors to ensure compliance with the federal and/or state bottled water regulations.

Beyond these government inspection programs, IBWA requires its member bottlers to submit to an annual inspection by an independent, third party organization as a condition of membership. IBWA members are inspected for compliance with the IBWA Code of Practice, which includes all FDA regulations as well as several more stringent requirements. The current inspection companies are Underwriter Laboratories (UL) and NSF International (NSF). IBWA bottler members must agree to a third party inspection by one of these two companies when they join or renew their membership.

IBWA members have embraced inspections as a method of enhancing a company's compliance and quality programs through the IBWA Code of Practice and its annual independent third party inspection program. This IBWA program has evolved (and continues to do so) as the industry and technology have changed, and new scientific developments have provided new information that will improve the safety and quality of bottled water.

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[20] 21 U.S.C. § 342.
[21] 21 U.S.C § 334.
[22] 21 C.F.R. 165.110 (a)(2)(ii)
[23] National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule, 71 Fed. Reg. § 653 (2006).

For many of our members, the IBWA inspection program is just one of many to which their facilities are subjected each year. FDA has included bottled water in many of its efforts to secure the food and agriculture critical infrastructure. Bottled water has been classified by FDA as warranting increased scrutiny to guard against security risks. In addition, state and federal agencies have inspected bottled water facilities with increased regularity. Within the private sector, retailers and distributors have also increased their oversight of their supplier network, as have manufacturers and processors have for their suppliers. IBWA welcomes this oversight, and is working with its members, customers and suppliers to better coordinate, manage and standardize the quality and quantity of inspections. IBWA is looking to such programs as the Global Food Safety Initiative, which is a world-wide effort to enhance food safety standards, to assist us in this effort.

HR 2749, as amended, would provide for risk based frequency for inspections by FDA. IBWA supports this approach because it should provide a better allocation of FDA resources to be dedicated to higher risk food categories than lower risk food categories. Increased frequencies of inspections would be welcomed by IBWA members. IBWA members are currently required, as a condition of membership to undergo annual inspections by an independent third party. Unfortunately, not all bottled water companies in the United States are subjected to this standard. Inspection frequency would be particularly important as FDA implements the hazard analysis and preventative controls provisions of HR 2749.

FDA Enforcement

The FDA Standards of Identity and Standards of Quality apply to each container of bottled water. If a bottled water product contains a contaminant that exceeds an FDA "Standard of Quality", the product must be labeled to reflect this substandard condition (e.g., "contains excessive _____").[24] Failure of a bottled water container to meet the standards of quality and to be properly labeled may subject it to recall by the company and removal from the market place. Further, and most importantly, if a bottled water product contains a contaminant that exceeds the Standard of Quality and it may be injurious to health, such product may be considered adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA) and subject to FDA enforcement action even if its label discloses the contaminant. The following tools are available to FDA in its enforcement of bottled water regulations:

- Pursuant to section 704 of the FFDCA (21 USC § 374), FDA may inspect any food manufacturing facility, including a bottled water plant.
- In the event a product is deemed misbranded or adulterated, FDA generally seeks voluntary compliance through the use of warning letters and requests for voluntary recalls.
- If the company declines to comply with applicable requirements or declines to take action to correct the violation, FDA may take civil action through either seizure or

[24] 21 C.F.R. § 165.110(c), 21 U.S.C. § 343(h)(1)

injunction. Depending on the circumstances, a criminal prosecution may also be warranted.[25]

- FDA may also use its authority to warn the public (e.g., press releases) or to publicize a product recall.
- Finally, under a new law passed just last year creating a reportable food registry, all food and beverage companies will be required to report to FDA whenever they have evidence showing a reasonable probability that their product may cause serious adverse health consequences or death, and FDA may take enforcement action if a company fails to do so.

IBWA supports granting FDA authority to mandate a recall under circumstances where an article of food presents an imminent threat of serious adverse health consequences or death. IBWA supports the provisions of HR 2749, which provide due process protections and limitations on FDA's authority to issue recalls, subpoenas, civil penalties and quarantine orders. These new enforcement authorities, along with the ability to suspend a facility's registration, would provide FDA with a wide choice of options to assist them in enforcing the U.S. food safety laws and substantially improving compliance by food companies.

FDA Has Jurisdiction Over Intrastate and Interstate Commerce

FDA's jurisdiction over bottled water products (and any other product regulated by FDA) extends not only to those products that move in interstate commerce, but to those products sold within a single state that are enclosed in packaging materials that have moved in interstate commerce. Known as the component theory of FDA jurisdiction, courts have long held that if a component of a food product moves in interstate commerce, FDA has jurisdiction over the finished product, regardless of whether the finished product itself moves in interstate commerce. This is because it is a violation of the FFDCA to adulterate or misbrand a food while it is held for sale after shipping in interstate commerce. [26] This position is well established by judicial opinion.

For example, in United States v. An Article of Food, 752 F.2d 11 (1st Cir. 1985), FDA brought a seizure and condemnation action against three lots of bottled soft drinks on the premises of a beverage producer in Puerto Rico. FDA contended that the beverages were adulterated because they contained an unapproved food additive (i.e., potassium nitrate). The bottler conceded that the beverages contained potassium nitrate but argued that FDA lacked jurisdiction because, although the potassium nitrate had been shipped in interstate commerce before addition to the beverages, the beverages had not. The court quickly disposed of the argument, commenting that "the 'shipment in interstate commerce' requirement is satisfied when adulterated articles held for in-state sale contain ingredients shipped in interstate commerce."[27]

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[25] 21 U.S.C. § 333(a).). Indeed, responsible officials of a food company may face criminal penalties for any violation of the FFDCA by the company, even if there was no "intent" to violate the law. *United States v. Park,* 421 U.S. 658 (1975).

[26] 21 U.S.C. § 331(k).

[27] An Article of Food, 752 F. 2d at 15 (citations omitted). This is only one in a long series of federal court decisions concluding that interstate shipment of a component of a food subjects the finished food to FDA jurisdiction. See also U.S. v. Sullivan, 332 U.S. 689 (1948) (labeling requirements of the Act apply to druggist who obtained drug product

The necessary interstate commerce element would likewise be satisfied based only on a component of a food product where the component is not edible, such as food packaging.[28] Indeed, IBWA is confident, based on the judicial precedent discussed above, that a court, if asked, would likely conclude that FDA has jurisdiction over bottled water if the bottle or other material used to package the water had been shipped in interstate commerce, even if the bottled water itself was processed and sold exclusively within the boundaries of a particular state.

Moreover, the FFDCA was amended in 1997 to create a statutory presumption that all FDA-regulated products have traveled in interstate commerce. Thus, FDA no longer needs to establish the interstate commerce element to assert jurisdiction. 21 U.S.C. § 379(a) states, "In any action to enforce the requirements of this Act respecting a device, food, drug or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist."

IV. Consumer Access to Bottled Water Information

IBWA supports a consumer's right to clear, accurate and comprehensive information about the bottled water products they purchase. IBWA agrees with the conclusion in FDA's 2000 Final Study Report, titled *"Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water"* (the "Feasibility Study Report") that placing on bottled water labels all of the information contained in the Consumer Confidence Reports (CCRs) provided by public water systems is not feasible for many reasons, including limited space available.[29] IBWA believes the most feasible mechanism for consumers to obtain this information is through a request to the bottler or distributor.

The FDA Feasibility Study Report looked at various ways that bottled water information could be communicated to consumers, including company contact information on the label, placing specific contaminant and other information on the label, distributing pamphlets at the point of

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in bulk and repackaged it for intrastate sale where bulk product had previously moved in interstate commerce); U.S. v. Dianovin Pharmaceuticals, Inc., 475 F.2d 100 (1st Cir. 1973) (injectable form of vitamin K constituted drug held for sale after shipment in interstate commerce where components had moved in interstate commerce; United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971) (finding bakers who sell bread and rolls made from flour shipped in interstate commerce are subject to prosecution for placing the flour in insect-contaminated equipment, thereby adulterating it); U.S. v. Detroit Vital Foods, Inc., 330 F.2d 78 (6th Cir. 1964) (finding misbranded tablets constituted drug held for sale after shipment in interstate commerce because ingredients had been shipped in interstate commerce); United States v. 40 Cases, More or Less, of Pinocchio Brand . . . Oil, 289 F.2d 343 (2d Cir. 1961) (concluding FDA has authority to proceed against misbranded or adulterated cans of vegetable oil that were mixed entirely within New York state from properly labeled oils shipped in interstate commerce), United States v. Varela-Cruz, 66 F. Supp. 2d 274 (D. Puerto Rico 1999) (rejecting defendants' contention that FDA lacked authority to prosecute milk adulteration case because the salt used to economically adulterate milk had traveled in interstate commerce, thereby providing necessary interstate commerce element).

[28] Cf. Baker v. U.S., 932 F.2d 813, 814, 816 (9th Cir. 1991) (finding that "shipment in interstate commerce" occurs "even when only an ingredient is transported interstate" and that "whether the ingredient is a main one or a minor one . . .is inconsequential"); U.S. v. Miami Serpentarium Lab., Food Drug Cosm. L.J. (CCH 38, 164 (S.D. Fl. 1982) (finding federal jurisdiction even when the "interstate constituent comprises only a minute fraction of the article" and that "it is immaterial whether the ingredient is characterized as 'active' or 'inactive.'").

[29] 65 Fed. Reg. § 51833-51839 (2000)

purchase and providing information via the internet. With regard to the feasibility of providing the same information on a bottled water label that is contained in CCRs provided by public water systems, FDA concluded that:

> "We agree with comments that stated it is not feasible to provide all of the information that is analogous to that contained in a CCR on a bottled water label. Such information would be excessive in limited label space, particularly on the small, single serving bottles. In addition, information that requires frequent changes due to changing test results may result in a misbranded product. Costs of frequent label changes that are necessary to ensure accurate information on the contents of a bottled water product, due to frequently changing information, may present an economic hardship to companies. Moreover, even annual updates that represent the contaminant history would need information to put the history for all such CCR-type information in context for the consumer and would be excessive in limited label space."[30]

IBWA believes that consumers should have timely and easy access to information about their bottled water products. To help ensure that consumers have access to useful and meaningful bottled water product information, the IBWA Code of Practice requires all members to comply with the following:

- All proprietary brand products must include a telephone number on their labels so consumers can easily contact the company and request product information. (In 2001, IBWA submitted a petition to FDA requesting that the Agency require a phone number to be listed on the label of all bottled water products.)
- IBWA maintains an online member database, which also contains a specific link to a member company's water quality information and/or contact information that may be used to secure a company's water quality report.

IBWA offers counsel to bottlers as to how to prepare and present water quality reports. Such assistance is provided one-on-one with bottlers; in educational sessions at national, regional, or local bottled water industry meetings; and in monthly, weekly, and targeted publications. IBWA makes available to its members an online Water Quality Reporting Template, which users may download and enter extensive water quality reporting information based on analytical testing results for all regulated parameters. IBWA provides either company contact information, a link to the company website for contact purposes or a direct link to water analysis data by brand on the IBWA website: www.bottledwater.org

Disclosures, such as those required by EPA in Consumer Confidence Reports for public water systems, are not required of any food or beverage product. These products must meet the safety standards and must be manufactured according to FDA regulations. However, bottled water companies voluntarily provide consumers with easy access to information about their products.

[30] 65 Fed. Reg. § 51836 (2000)

As mentioned earlier, consumers have a plethora of choices in brands of bottled water. That is not the case with their public water system. Consumers cannot make a choice of which municipal water is piped into their homes. If a bottled water company does not satisfy a consumer's request for more information, that consumer is free to make other brand choices. Such requests are not a matter of consumer safety because a bottled water product that does not meet the FDA Standards of Quality, which are the health-based standard for bottled water, may not stay in the market place and is subject to enforcement action by the FDA

V. Environmental Impact of Bottled Water

The bottled water industry is strongly committed to stewardship of the environment. Whether it is developing groundwater protection areas, supporting state groundwater management programs or developing new technology to reduce the plastic needed for its containers, the bottled water industry has been on the forefront of innovation in the food and beverage industry in developing policies and technology to promote environmental stewardship. IBWA is dedicated to the comprehensive management of bottled water packaging to provide the highest quality, cost effective and environmentally responsible containers possible. IBWA and its members approach packaging issues in a manner emphasizing the most effective and efficient solutions to reduce the impact on the environment, while taking into account the equal responsibility of all solid waste generators. Consideration must also be given to behavioral solutions, such as public education and enforcement of existing recycling and litter control laws.

Packaging

IBWA and its members believe a comprehensive approach must be utilized, emphasizing efficient and effective solutions that address the broad array of solid waste and treat all solid waste, including waste from all food and beverage products, in an equitable manner. IBWA believes the following set of principles should be a guide in addressing solid waste, recycling and litter:

- Education and awareness - Behavioral approaches to solid waste reduction and litter control must be a part of any good public policy.
- Efficient, yet effective, solutions - Programs that more properly balance cost and convenience with effectiveness should be given a higher priority.
- Curbside recycling programs – Improvements and expansion of curbside recycling and venue recycling opportunities need to be addressed.
- Equitable treatment for all waste producers - In order to effectively address the total municipal solid waste stream, proper solutions must look beyond just beverage containers.

Bottled water is one of thousands of food and beverage products that are packaged in plastic containers. Members of IBWA recognize their responsibility for their containers and are taking steps to mitigate its environmental impact. These steps will be outlined later in this testimony. However, the issue of environmental impact of plastic containers and the impact of those containers on community landfills is not solely to be borne by the bottled water industry, but

rather the producers of all consumer products. In addition, the debate must also include how do we, as a nation, increase the recycling rates and capture more of the plastic packaging for reuse. Plastic bottles that enter the recycling stream provide a valuable, sought after feedstock for numerous other consumer products.

The bottled water industry has one segment that has a uniquely positive story on reuse and recycling. The home and office delivery segment of the bottled water industry uses primarily three and five gallon plastic containers that are routinely returned, sanitized and reused from 20 to 40 times. The bottles are then sent by the bottler to be recycled. Almost 100% of these containers are first reused, and then recycled, and the processed plastic is made into a wide variety of different products. As indicated earlier in this testimony, the home and office delivery segment of the bottled water represents about 20% of the industry. IBWA is not aware of any other industry that experiences this incredible reuse and recycling rate.

For the retail market segment of the bottled water industry, the most common plastic used is PET, although HDPE and other plastics are used as well. These containers are fully recyclable and the value of the recycled plastic has been steadily increasing. However, bottled water is only one of many consumer products that use PET plastic in the production of the product. To put the issue in perspective, in 2006 a total of 244 billion units of ready-to-drink beverages were sold, and only 33% of those units were packaged in plastic (see attached Chart I). A total of 36 billion units of bottled water were sold in 2006, amounting to only 15% of all beverage units sold. That means that 85% of all the beverage units sold in 2006 were for products *other than* bottled water.

With regard to the lack of recycling of beverage units, bottled water critics claim that our products are filling up municipal landfills. Beverage containers are recycled at an overall rate of approximately 25%, a much higher rate than other food containers, and that rate continues to increase. Bottled water containers, as a subset of all beverage containers, has a recycling rate of approximately 23%. However, bottled water containers make up only 0.3% of the entire municipal waste stream in the United States (see attached Chart II). Clearly, bottled water containers are not significantly contributing to municipal landfills. Significant overall progress with recycling and the management of municipal waste streams cannot be made unless the public policy net is cast much more broadly than just bottled water. Efficiently capturing and recycling of *all* plastic products should be a priority.

The national recycling rate for PET plastic bottled water containers (.5 liter or 16.9 ounce size) has improved by 16.42%, according to new data from two new studies: “2008 Post Consumer PET Bottle Bale Composition Analysis” and “2007 Report on PET Water Bottle Recycling,” both produced by the National Association for PET Container Resources (NAPCOR). According to data from an earlier 2006 bale content study for all beverages, the number of PET bottles counted per pound was approximately 12. In 2008, the total number of PET bottles increased to 13.78, a reflection of the dramatic increase in water bottle collection, as well as the continued lightweighting of other plastic containers. The 2007 NAPCOR study on water bottle recycling has determined that the recycling rate for water bottles is 23.4%, representing a significant 16.42% increase over the 2006 recycling rate of 20.1%.

With data compiled during an extensive bale composition study in 15 locations in 14 states, the 2008 NAPCOR PET analysis states: "Water bottles are now the most recycling container in curbside programs by weight, and overwhelmingly by number." PET water bottles now account for 50% of all the PET bottles and containers collected by curbside recycling. This trend was consistent in all curbside bales sampled nationally, with no major shifts observed in any other plastic container category. The biggest jump in water bottle collection for recycling was in California, where a state-funded consumer education campaign, emphasizing that water bottles are recyclable, seems to be having the desired effect.

In tandem with the new NAPCOR data, IBWA tracked the average amount of plastic used in .5 liter (16.9 ounce) PET bottles, using published data from the Beverage Marketing Corporation (BMC) to determine the light-weighting trend currently being seen in many brands of bottled water. In the year 2000, the average weight of a plastic water bottle was 18.90 grams. It has declined consistently on an annual basis and by 2007, the last year BMC has complete data (as of this date), the average weight of a PET water bottle was 13.83 grams – a 26.7% decline.

The bottled water industry recognizes that the recycling rate for bottled water containers is not satisfactory. IBWA has joined with the American Beverage Association, the Food Marketing Institute, the Grocery Manufacturers Association and the National Recycling Coalition in the National Recycling Partnership to fund a pilot project in Hartford, Connecticut. The pilot project will measure the impact of having single stream collection with consumer financial incentives to recycle. The pilot project is utilizing Recycle Bank. Recycle Bank provides monetary credits on individual debit cards to each participating household for the amount that they recycle. We are hopeful that this project will demonstrate a means to increase community recycling rates, while lowering the impact on landfills. The project was launched in May of 2008, and the preliminary results have been very promising: volumes recycled by the pilot households more than doubled from the pre-pilot volumes and the average quantity of recycled material also doubled. In addition, the Partnership joined with the United States Environmental Protection Agency (EPA) in funding research on rebranding recycling. This is just one of many efforts in communities throughout the United States to increase the recycling rates.

More still needs to be done. In 1999, almost 1000 communities around the country provided their citizens with curbside recycling. However, less than 900 communities offer this service today. Rather than fewer communities providing curbside recycling, more communities should be encouraged to establish curbside programs and promote recycling within their jurisdictions. We all can play a role in making this happen and the bottled water industry stands willing to work with others to enhance community recycling. Many of IBWA members donate bottled water to community events, such as fundraising efforts or community promotional events. They often condition the donation on the event sponsor providing recycling opportunities at the event.

As part of the environmental stewardship of the bottled water industry, innovations and new technologies are being developed to reduce the environmental impact of the industry. Examples of such innovation can be seen in the container, itself. As discussed above, the PET bottled water container is produced using far less plastic than it did 10 years ago. This innovation is readily apparent to consumers as they can actually feel the difference in their bottled water container.

Second, many bottled water companies are using some recycled PET material when making their plastic bottles. This reduces the amount of virgin material necessary to make these containers. And third, new technologies are being developed to allow bottlers to use a "compostable" container made from corn. Bottled water is one of only a few food products that have begun to be packaged in this type of container, and a few IBWA members now use this type container for bottled water. Since it is relatively new to the market, the use of this new technology may increase over the next few years.

The bottled water industry should be recognized and supported in its efforts to innovate and find solutions to reducing the environmental impact of its product. Like all manufacturers of consumer goods, the industry is finding new ways to reduce the amount of petroleum used to deliver its product to market, whether using hybrid trucks or configuring delivery routes. These efforts are ongoing and vital to the continued economic health of the industry.

VI. Water Stewardship

Groundwater is the primary water source for bottled water products sold in the United States. Because a long-term sustainable supply of high-quality water is literally the foundation and "lifeblood" of bottled water companies, IBWA member bottlers recognize the critical importance of environmental conservation and stewardship of all water resources. Bottled water companies perform hydro-geological assessments, monitor the quality and quantity at source wells, purchase surrounding land for protection and recharge of their source and participate in local and regional water stewardship partnerships on aquifer protection.

Groundwater is a renewable natural resource that is replenished through the hydrologic cycle. The duration of the replenishment cycle is influenced by weather patterns, recharge areas and characteristics, geologic settings and other site-specific factors. When developing and using water resources, it is essential that use is balanced with the replenishment cycle and the requirements of the regional demand for the resource. IBWA supports groundwater management policies, laws and regulations that are comprehensive, science-based, multi-jurisdictional, treat all users equitably, and balance the rights of current users against the future needs to provide a sustainable resource.

The bottled water industry uses minimal amounts of ground water to produce an important consumer product—and does so with great efficiency. According to a 2005 study by the Drinking Water Research Foundation (DWRF), annual bottled water production accounts for less than 2/100 of one percent (0.02%) of the total groundwater withdrawn in the United States each year.[31] Additionally, based on information gathered in the DWRF study, in 2001, 87% of the water withdrawn by bottled water companies, on average, was actually bottled for consumption by humans, so the bottling process is a very efficient one.[32]

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[31] Drinking Water Research Foundation, 2005, *Bottled Water Production in the United States: How Much Groundwater Is Actually Being Used?*
[32] Id.

VII. Bottled Water Plays a Vital Role in Disaster Response

Clean, safe water is a critical need for citizens and first responders immediately following a natural disaster or other catastrophic event. Unfortunately, the availability of water from public water systems is often compromised in the aftermath of such an event. During these times, bottled water is the best option to deliver clean safe drinking water quickly into affected areas.

The bottled water industry has always been at the forefront of relief efforts during natural disasters and other catastrophic events. Throughout the years, bottled water companies have immediately responded to the need for clean water after natural disasters, such as Hurricanes Andrew, Charlie, and Katrina, the earthquakes and forest fires in the West, or the terrorist attacks on the Pentagon and World Trade Center. Our companies also provided bottled water to those in need last year in the aftermath of the spring flooding in the Midwest and to the victims of Hurricanes Gustav and Hanna.

The bottled water industry looks to IBWA to help coordinate activities with state and federal government agencies and organizations, such as the American Red Cross and Salvation Army. Working together, we determine the quickest and most effective way to deliver safe bottled water into affected areas to augment other relief efforts.

An example of this experience was the bottled water industry's response to the September 11, 2001, attacks on the Pentagon and World Trade Center. IBWA worked with the Salvation Army in identifying a staging area in Northern Virginia for bottled water being delivered to the Pentagon. The industry began shipping product to that staging area in the afternoon of September 11, 2001. In addition, IBWA identified one of its member companies' facilities on the western shore of the Hudson River as a staging area for bottled water being delivered across the river to "ground zero" in New York City. IBWA then notified its member bottlers of this location and they began shipping bottled water to the facility before the end of the day. IBWA also worked with the Federal Emergency Management Agency (FEMA) and National Guard so that bottled water and other goods could be staged at the facility and transported into New York City.

Another example is Hurricane Katrina, a tragic disaster that impacted millions of Americans. IBWA and its members were actively involved in responding to this monumental disaster. From IBWA members personally driving truckloads of bottled water and other relief supplies into affected areas, to shipments of multiple truckloads to remote communities—in many cases as the first responders on the scene—to the execution of staff/member partnerships to help identify and make arrangements with stricken communities for direct relief deliveries, the bottled water industry stepped up to the plate to donate products to those in need. IBWA members provided tens of millions of bottled water servings, ranging from 16-ounce bottles to five gallon bottled water cooler containers in the aftermath of Hurricane Katrina. This is in addition to the tankers of bulk drinking water supplied by IBWA bottlers and the tens of millions of servings provided through the relief organizations, state emergency management agencies and the Federal Emergency Management Agency.

Bottled water companies have also worked with municipal water systems to provide the public with clean, safe bottled water when the public drinking water infrastructure is compromised or when the water does not meet state and federal health standards. An example of such a situation occurred last year in Washington, DC, when lead levels in some parts of the public water supply exceeded the action level set by the United States Environmental Protection Agency (EPA). Bottled water and point-of-use systems were used to meet the drinking water needs in the affected area until the Washington Area Sanitation Commission was able to reduce the lead levels to meet EPA standards.

The efforts of the industry to provide crucial drinking water to citizens afflicted by disasters are contingent on a viable commercial market. The commercial market provides them with the capital and resources to respond when needed. The industry cannot exist only for disaster response as some industry critics would have people believe. The need for such philanthropic efforts can only be seen when people need it the most. To discourage the use of bottled water or question the safety of bottled water does a disservice to an industry that is called upon every year to provide much needed drinking water.

VIII. Conclusion

Bottled water provides consumers with a convenient, healthy beverage choice. The standards of quality for bottled water are as protective of public health as those for public drinking water by law and practice. Such standards for bottled water are applied to each container and failure to meet those standards may result in a recall or FDA enforcement action. If a consumer is interested about what is in their bottled water, they have multiple methods of obtaining it, e.g., from the company website, contacting the company directly, researching state websites which post the information or IBWA's website. If they are not satisfied with the response or the information provided, they have many choices among bottled water brands.

IBWA appreciates the opportunity to provide the Subcommittee with this overview of the bottled water industry. If you would like more information or have further questions, please feel free to contact us.

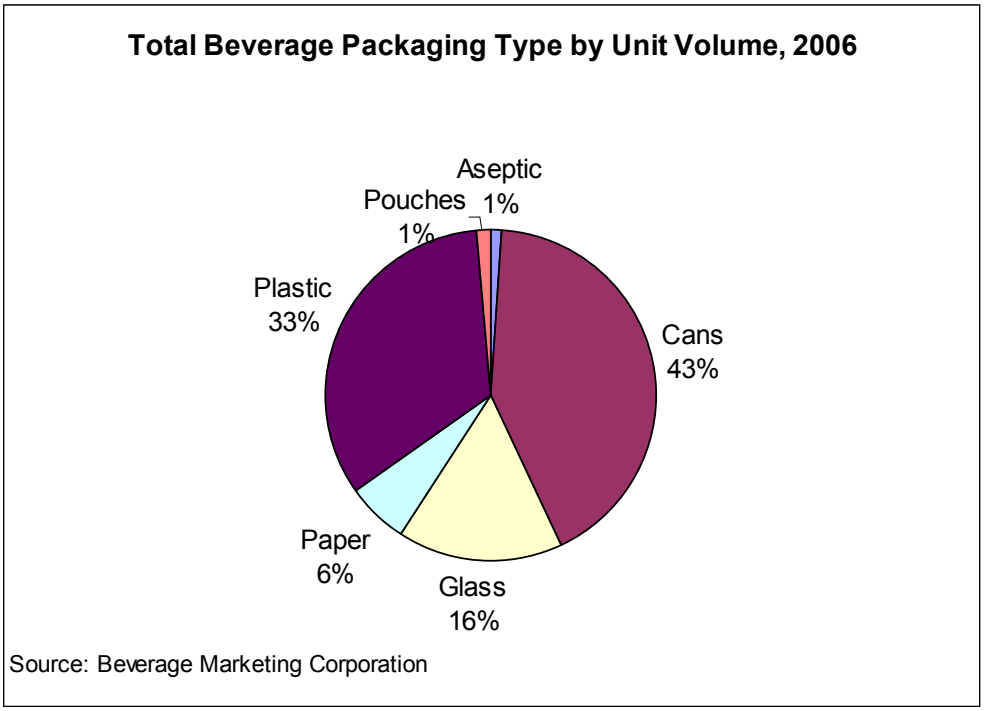

Chart I

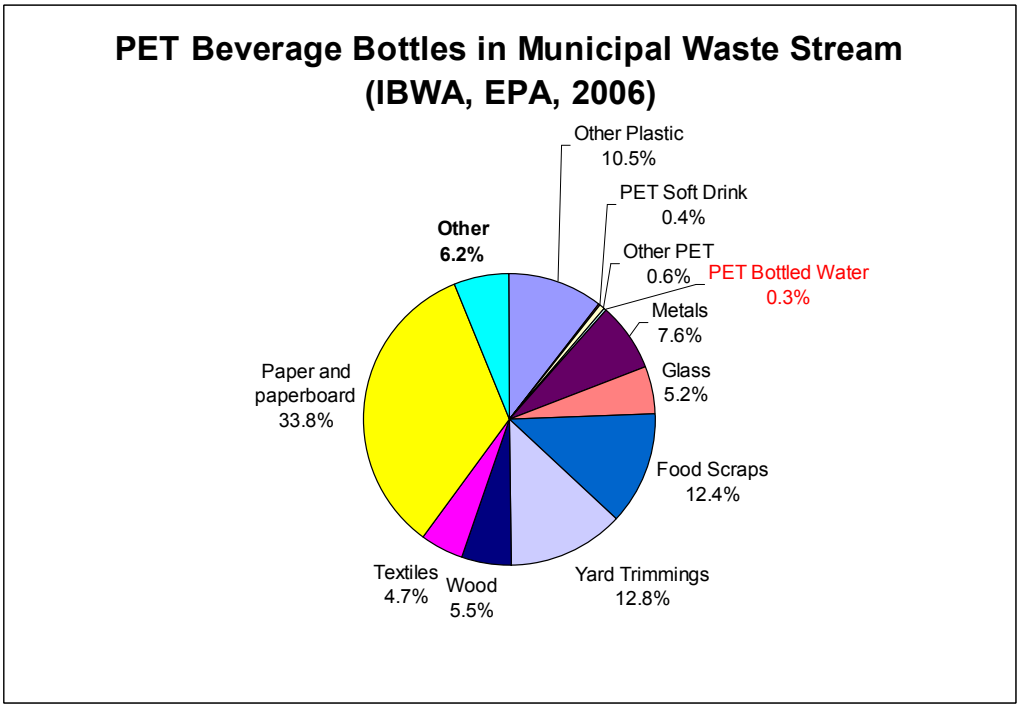

Chart II

Model Code

International Bottled Water Association

Bottled Water Code of Practice

Revised January, 2007

International Bottled Water Association
1700 Diagonal Road, Suite 650
Alexandria, VA 22314
(703) 683-5213
http://www.bottledwater.org

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP *Individual Group Analytes*	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Inorganic Chemicals (IOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Antimony (1)	(Product and Source)	0.006	0.006	0.006
Arsenic		0.01	0.05	0.05
Barium	For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	1	2	2
Beryllium (1)		0.004	0.004	0.004
Bromate (2)		0.010	0.010	0.010
Cadmium		0.005	0.005	0.005
Chlorine (2)		0.1	4.0	4.0
Chloramine (2)		4.0	4.0	4.0
Chlorine dioxide (2)		0.8	0.8	0.8
Chlorite (2)		1.0	1.0	1.0
Chromium		0.05	0.1	0.1
Cyanide (1)		0.1	0.1	0.2
Fluoride		(3)	(3)	4
Lead		0.005	0.005	0.015 AL
Mercury		0.001	0.002	0.002
Nickel (1)		0.1	0.1	
Nitrate-N		10	10	10
Nitrite-N		1	1	1
Total Nitrate + Nitrite		10	10	10
Selenium		0.01	0.05	0.05
Thallium (1)		0.002	0.002	0.002
Secondary Inorganic Parameters	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**SMCL (4)**
Aluminum	(Product and Source)	0.2	0.2	0.2
Chloride (5)		250	250	250
Copper		1	1	1 AL
Iron (5)		0.3	0.3	0.3
Manganese (5)		0.05	0.05	0.05
Silver		0.025	0.1	0.1
Sulfate (5)		250	250	250
Total Dissolved Solids (TDS) (5)		500	500	500
Zinc (5)		5	5	5
Volatile Organic Chemicals (VOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
1,1,1-Trichloroethane	(Product and Source)	0.03	0.2	0.2
1,1,2-Trichloroethane		0.003	0.005	0.005
1,1-Dichloroethylene	For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	0.002	0.007	0.007
1,2,4-Trichlorobenzene		0.009	0.07	0.07
1,2-Dichloroethane		0.002	0.005	0.005
1,2-Dichloropropane		0.005	0.005	0.005
Benzene		0.001	0.005	0.005
Carbon tetrachloride		0.005	0.005	0.005
cis-1,2-Dichloroethylene		0.07	0.07	0.07
trans-1,2-Dichloroethylene		0.1	0.1	0.1
Ethylbenzene		0.7	0.7	0.7
Methylene chloride (Dichloromethane)		0.003	0.005	0.005
Monochlorobenzene		0.05	0.1	0.1
o-Dichlorobenzene		0.6	0.6	0.6
p-Dichlorobenzene		0.075	0.075	0.075
Haloacetic Acids (HAA5) (2)		0.06	0.06	0.06
Styrene		0.1	0.1	0.1

(1) Included in FDA's 9 contaminant regulations.
(2) Included in FDA's D/DBP rule. See D/DBP monitoring requirements section on page 21 in Appendix A for details.
(3) SOQ dependent upon temperature and other factors. See fluoride section on page 22 of Appendix A for details.
(4) SMCL = Secondary maximum contaminant level. SMCLs are guidelines established by the USEPA for use in evaluating aesthetic, non-health-related properties in water. SMCLs are not enforceable for public water systems.
(5) Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP *Individual Group Analytes*	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Volatile Organic Chemicals (VOCs) (Continued)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Tetrachloroethylene	(Product and Source)	0.001	0.005	0.005
Toluene		1	1	1
Trichloroethylene	For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	0.001	0.005	0.005
Vinyl chloride		0.002	0.002	0.002
Xylenes (total)		1	10	10
Bromodichloromethane		(6)	(6)	(6)
Chlorodibromomethane		(6)	(6)	(6)
Chloroform		(6)	(6)	(6)
Bromoform		(6)	(6)	(6)
Total Trihalomethanes (2)		0.01	0.08	0.08
Semivolatile Organic Chemicals (SVOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Benzo(a)pyrene	(Product and Source)	0.0002	0.0002	0.0002
Di(2-ethyhexyl)adipate		0.4	0.4	0.4
Di(2-ethyhexyl)phthalate		0.006	NA	0.006
Hexachlorobenzene		0.001	0.001	0.001
Hexachlorocyclopentadiene		0.05	0.05	0.05
Total Recoverable Phenolics		0.001	0.001	NA
Synthetic Organic Chemicals (SOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
2,4,5-TP (Silvex)	(Product and Source) (unless otherwise noted)	0.01	0.05	0.05
2,4-D (Dichlorophenoxy acetic acid)		0.07	0.07	0.07
Alachlor		0.002	0.002	0.002
Aldicarb		0.003	NA	0.003
Aldicarb sulfone		0.003	NA	0.003
Aldicarb sulfoxide		0.004	NA	0.004
Atrazine		0.003	0.003	0.003
Carbofuran		0.04	0.04	0.04
Chlordane		0.002	0.002	0.002
Dalapon		0.2	0.2	0.2
Dibromochloropropane (DBCP)		0.0002	0.0002	0.0002
Dinoseb		0.007	0.007	0.007
Dioxin (2,3,7,8-Tetrachlorodibenzo-p-dioxin) (1)(7)	Product: Every 3 years Source: Annually	$3x10^{-8}$	$3x10^{-8}$	$3x10^{-8}$
Diquat (1)(7)		0.02	0.02	0.02
Endothall (1)(7)		0.1	0.1	0.1
Endrin	ANNUALLY	0.002	0.002	0.002
Ethylene dibromide	(Product and Source)	0.00005	0.00005	0.00005
Glyphosate (1)(7)	Product: Every 3 years Source: Annually	0.7	0.7	0.7
Heptachlor	ANNUALLY	0.0004	0.0004	0.0004
Heptachlor epoxide	(Product and Source)	0.0002	0.0002	0.0002
Lindane		0.0002	0.0002	0.0002
Methoxychlor		0.04	0.04	0.04
Oxamyl (vydate)		0.2	0.2	0.2
Pentachlorophenol		0.001	0.001	0.001
Picloram		0.5	0.5	0.5
Polychlorinated biphenyls (PCBs)		0.0005	0.0005	0.0005
Simazine		0.004	0.004	0.004
Toxaphene		0.003	0.003	0.003

(1) Included in FDA's 9 contaminant regulations.
(2) Included in FDA's D/DBP Rule. See D/DBP monitoring requirements section in Appendix A for details.
(6) No SOQs or MCLs established for individual trihalomethane contaminants. The sum of the 4 THMs is regulated as total trihalomethanes (TTHMs).
(7) FDA requires that the four synthetic organic chemicals (SOC) listed must be tested quarterly for four consecutive quarters for each type of finished bottled water (e.g., spring, purified, etc.). If none of the SOCs are detected, then once every three years for each type of finished product. If SOCs are detected, maintain monitoring for four consecutive quarters in each three-year period. New products and new companies must do an initial round of quarterly monitoring in the first year of operation.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

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MONITORING PARAMETER GROUP *Individual Group Analytes*	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Additional Regulated Contaminants	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Methyl tertiary butyl ether (MTBE)	(Product and Source)	0.07	NA	NA
Naphthalene		0.3	NA	NA
1,1,2,2-Tetrachloroethane		0.001	NA	NA
Microbiological Contaminants		**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Total coliform / *E. coli*	SOURCE: at least once each week (21 CFR §129.35(a)(3)) PRODUCT: at least once each week (21 CFR §129.35(g)(1))	No *Eschericia coli* detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by resampling. NOTE: Confirmation AND validation of all positive total colifrm results in finished product required. See Appendix C of the Model Code.	**MPN:** <2.2 organisms per 100 ml. **MF:** <4 CFU per 100 ml.	No more than 5% of monthly samples valid for total coliform.
Radiological Contaminants	SEE BELOW	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Gross Alpha Particle Radioactivity	SOURCE: Annually PRODUCT: Every 4 years	15 pCi/L	15 pCi/L	15 pCi/L
Gross Beta Particle and Photon Radioactivity (8)		50 pCi/L	50 pCi/L	50 pCi/L
Radium 226/228 (combined)	SOURCE: Annually PRODUCT: Every 4 years	5 pCi/L	5 pCi/L	5 pCi/L
Uranium	SOURCE: Annually PRODUCT: Every 4 years	0.030	0.030	0.030
Water Properties	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**GUIDELINE**
Color	(Product and Source)	5 Units	15 Units	5 Units
Turbidity		0.5 NTU	5.0 NTU	0.5 NTU
'pH (9)		5-7/6.5-8.5	NA	6.5-8.5
Odor		3 T.O.N.	3 T.O.N.	3 T.O.N.

(8) If the gross beta particle activity exceeds 50 pCi/1, an analysis of the sample must be performed to identify the major radioactive constituents present. Compliance (with § 141.16) may be assumed without further analysis if the average annual concentration of gross beta particle activity is less than 50 pCi/1 and if the average annual concentrations of tritium and strontium–90 are less than those listed in table A, *Provided,* That if both radionuclides are present the sum of their annual dose equivalents to bone marrow shall not exceed 4 millirem/year. Consult with your testing laboratory for more information.

(9) The Model Code guideline for pH in purified water is 5.0-7.0 (see Appendix B for definition and requirements for purified water). The guideline for source water and other product waters is 6.5-8.5. NOTE: This guideline is not enforceable.

All SOQs, MCLs, SMCLs, and guidelines in mg/L(ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix A
2007 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

FDA D/DBP Rule Monitoring Requirements

Public Water System (PWS) Source Water

If current PWS D/DBP data is available, no source water analysis is required.

If current PWS D/DBP data is NOT available, ANNUAL testing for the following is required:

- Disinfectants: Chlorine, Chloramine, Chlorine dioxide
- Disinfection Byproducts: Bromate, Chlorite, Haloacetic acids (HAA5), and Total Trihalomethanes (TTHMs)

Natural Water Sources

If no disinfection is applied at the source, including use in bulk water hauling, no source water analysis is required.

If disinfection is applied at the source, including use in bulk water hauling, ANNUAL testing for the following is required:

- The residual disinfectant used (chlorine, chloramine, or chlorine dioxide)
- Ozone: Bromate, Haloacetic acids (HAA5), Total Trihalomethanes (TTHMs)
- Chlorine-based disinfectants (chlorine, chloramine, or chlorine dioxide): Haloacetic acids (HAA5) and Total Trihalomethanes (TTHMs)

ALL FINISHED PRODUCTS

ANNUAL testing is required for ALL of the following in each finished product type:

- Chlorine
- Chloramine
- Chlorine dioxide
- Bromate
- Chlorite
- Haloacetic acids (HAA5)
- Total Trihalomethanes (TTHMs)

Appendix A
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FDA Requirements for Fluoride in Bottled Water

Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

*Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	2.4
53.8–58.3	2.2
58.4–63.8	2.0
63.9–70.6	1.8
70.7–79.2	1.6
79.3–90.5	1.4

Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these lev-els shall be based on the annual aver-age of maximum daily air tempera-tures at the location where the bottled water is sold at retail.

TABLE 2

*Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	1.7
53.8–58.3	1.5
58.4–63.8	1.3
63.9–70.6	1.2
70.7–79.2	1.0
79.3–90.5	0.8

Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

Comparison of US FDA SOQs and US EPA MCLs With IBWA Code of Practice SOQs *
(revised 7/2007)

MONITORING PARAMETER GROUP *Individual Group Analytes*	IBWA MONITORING FREQUENCY	SOCs, MCLs, SMCLs, and Guidelines		
Inorganic Chemicals (IOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Barium		1	2	2
Chlorine		0.1	4.0	4.0
Chromium		0.05	0.1	0.1
Lead		0.005	0.005	0.015 AL
Mercury		0.001	0.002	0.002
Nickel		0.1	0.1	
Selenium		0.01	0.05	0.05
Secondary Inorganic Parameters	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA SMCL**
Silver	(Product and Source)	0.025	0.1	NA
Volatile Organic Chemicals (VOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
1,1,1-Trichloroethane	(Product and Source)	0.03	0.2	0.2
1,1,2-Trichloroethane		0.003	0.005	0.005
1,1-Dichloroethylene		0.002	0.007	0.007
1,2,4-Trichlorobenzene		0.009	0.07	0.07
1,2-Dichloroethane		0.002	0.005	0.005
Benzene		0.001	0.005	0.005
Methylene chloride (Dichloromethane)		0.003	0.005	0.005
Monochlorobenzene		0.05	0.1	0.1
Tetrachloroethylene		0.001	0.005	0.005
Trichloroethylene		0.001	0.005	0.005
Total Trihalomethanes		0.01	0.08	0.08
Semivolatile Organic Chemicals (SVOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Di(2-ethyhexyl)phthalate	(Product and Source)	0.006	NA	0.006
Total Recoverable Phenolics		0.001	0.001	NA
Synthetic Organic Chemicals (SOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
2,4,5-TP (Silvex)	(Product and Source)	0.01	0.05	0.05
Aldicarb		0.003	NA	0.003
Aldicarb sulfone		0.003	NA	0.003
Aldicarb sulfoxide		0.004	NA	0.004
Additional Regulated Contaminants	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Methyl tertiary butyl ether (MTBE)	(Product and Source)	0.07	NA	NA
Naphthalene		0.3	NA	NA
1,1,2,2-Tetrachloroethane		0.001	NA	NA
Microbiological Contaminants	DAILY / WEEKLY AT APPROVED LAB	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Total coliform / *E. coli*	NOTE: Confirmation AND validation of all positive total coliform results required. SEE APPENDIX C OF THE MODEL CODE	No *Eschericia coli* detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by resampling.	**MPN:** <9.2 organisms per 100 ml. **MF:** <4 CFU per 100 ml.	No more than 5% of monthly samples valid for total coliform.
Water Properties	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**GUIDELINE**
Turbidity		0.5 NTU	5.0 NTU	0.5 NTU
'pH		5-7/6.5-8.5	NA	6.5-8.5

*The above is a list of contaminants for which IBWA has more stringent standards of quality then either FDA or the USEPA.